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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/485,438	06/07/1995	STEPHEN EISENBERG	65850-1103.2	5619
22852	7590	06/30/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			MOORE, WILLIAM W	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

08/485,438

Applicant(s)

EISENBERG ET AL.

Examiner

William W. Moore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Applicant's Amendment filed March 15, 2004, has been entered and cancellation of claims 12 and 13 therein overcomes the rejection of record under the second paragraph of 35 U.S.C. § 112. The amendment also adds new claims 14-35, amends page 1 of the specification to revise the continuing data for the instant application current, and amends page 5 to bodily incorporate disclosures of commonly-assigned U.S. Patent No. 4,760,130, earlier incorporated by reference at page 5 of the specification, that support the more particular recitations of the new claims 14-35. It is noted that the amendment to page 1 of the specification fails to state the status of the parent application serial No. 08/209,040. Applicant may correct this oversight in response to this communication.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14, 17-20, 23, 24, 29-33, and 35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 6,132,990. This is essentially the rejection of record, restated to correspond to the recitations of the new claims 14, 17-20, 23, 24, 29-33, and 35 added by Applicant's Amendment. Although the conflicting claims are not identical, they are

not patentably distinct from each other because the methods that are described by the new claims 14, 17-20, 23, 24, 29-23, and 35 for "inhibition of" viral or retroviral "proliferation which comprises treating a patient with . . . an" antiviral or antiretroviral "effective amount" of the serine protease inhibitor that is commonly structurally defined in claims of the instant application and the patent would extend, improperly, the exclusion of the public from practice of the generic method of the patented claim 12, "of treating a serine protease-mediated condition comprising a serine protease inhibitor", that is the same inhibitor commonly structurally defined in the new claims 14, 17-20, 23, 24, 29-23, and 35 herein and in claims 1-8 of the issued patent. Applicant suggests at pages 12-13 of the Response filed March 15, 2004, that the issued patent provides no disclosure supporting its claim 12 that would have made the subject matters of claims 14, 17-20, 23, 24, 29-23, and 35 herein obvious to one of ordinary skill in the art and argues that excluding the public from practice of methods of new claims 14, 17-20, 23, 24, 29-23, and 35 herein would not improperly extend the right to exclude the public from practice of the generic invention granted with claim 12 of the issued patent. Applicant cites *In re Kaplan*, 229 U.S.P.Q.2d 678 (Fed. Cir. 1986) - where the Federal Circuit reversed a double patenting rejection of a claim to a lesser-included process requiring a specific solvent mixture over a patented claim to a process using a generic solvent mixture - for the proposition that domination of a specific claim in a pending application by a broader, patented, claim is irrelevant. Applicant's argument indicates a belief that one of ordinary skill in the art would not consider methods of administering the commonly disclosed inhibitor to inhibit, thus treat, viral and retroviral proliferation to be the same as, or obvious variants of a process of administering the same inhibitor to treat a "serine protease-mediated condition". Yet the patented and presently-claimed inventions are inherently the same, and would be recognized as such by the artisan,

because the agent required to inhibit, thus treat, viral and retroviral proliferation is the same agent use to treating a treat a "serine protease-mediated condition", and because treating viral and retroviral proliferation with the inhibitor is disclosed to be the treatment of a serine protease-mediated condition with the inhibitor. Even though the issued patent discusses no more than treatment of medical conditions, such as pancreatitis, mediated by release of native serine proteases in tissues unbalanced by the presence of a countervailing, native, serine protease inhibitor, a patent issuing with claims 14, 17-20, 23, 24, 29-33, and 35 herein would extend the protection of the very same invention of the patented claim 12 because neither the patented claim nor the pending claims make a distinction between use of the same inhibitor to inhibit any particular serine protease, because neither the patented nor pending claims make a distinction between a serine protease that is released by a cell or that is maintained on or within a cell, and because the disclosures of the issued patent or the instant application do not permit such distinctions to be made.

Claims 14-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 and 17-25 of U.S. Patent No. 6,017,880. This is essentially the rejection of record, restated to correspond to the new claims 14-35 added with Applicant's Amendment. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods described by claims 14-35 pending herein of "inhibition of" viral or retroviral "proliferation which comprises treating a patient with . . . an" antiviral or antiretroviral "effective amount" of the serine protease inhibitor that is commonly structurally defined in claims of the instant application and the patent are obvious, generic, embodiments of narrower methods of the patented claims 13-25, "for treating retrovirus infection comprising treating a patient with an amount of" that inhibitor "sufficient to inhibit retrovirus infection

of CD4⁺ cells". Applicant indicates that a Terminal Disclaimer may be provided upon notice that other grounds of rejection are overcome, but the rejection must be made until an effective Terminal Disclaimer is submitted. The methods recited in the pending claims are merely more general statements of the same method recited in the patented claims, and this would have been obvious to such an artisan at the time the invention was made, where methods of administering serine protease inhibitors common to both the pending and patented claims to "inhibit [viral or retroviral proliferation] proliferation", according to the pending claims, are the methods of the patented claims that "inhibit retrovirus infection of CD4⁺ cells", since inhibition of viral, or retroviral, proliferation in a subject is a necessary consequence of inhibiting the retroviral infection of susceptible cells in a patient. Artisans of ordinary skill in the field of biology, indeed many lay persons, are well aware that neither viruses, nor the subgroup of retroviruses, are able to replicate, hence "proliferate", unless they successfully infect cells that support their replication and assembly, and such artisans, and the public, seeking to construe the claims pending herein would appreciate that the pending claims 14-35 and the patented claims 13-15 and 17-25 require the common inhibitor be administered to a patient and act on cells of the patient in order to serve in the methods narrowly stated in the patented claims as well as to serve in the same methods, more broadly cast in the claims rejected herein. Disclosures of the issued patent and the instant specification permit no distinction between methods of the pending claims from those of the patented claims and the rejection of record is sustained where the only difference between methods of the patented claims and pending claims is semantic.

Applicant's arguments filed March 15, 2004, with respect to the rejection of record of claims 12 and 13 been considered but they are not relevant to this rejection of the new claims 14-35. First, the situation Applicant argues is reversed where the patented

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claims 14-23 describe apparently narrower species, of methods and the pending claims 24-35 describe apparently broader methods. Second, the term of exclusive practice of methods of the patented claims would be unduly extended should methods described by the pending claims issue in a patent where the public would continue to be excluded from the practice of methods of claims now patented in attempting to practice methods of the less precisely worded claims pending herein because a method claimed herein of administering an antiviral effective amount of the common protease inhibitor to a patient to "inhibit viral proliferation" also constitutes a method of "treating a retrovirus infection", such as an HIV-1 infection of the patented claims 14 and 15, where the patent and the instant specification teach that the common protease inhibitor will "inhibit retrovirus infection of CD4⁺ cells", concomitantly inhibiting proliferation of the virus.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The fax phone numbers for all communications for the organization where this application or


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proceeding is assigned remains 703.872.9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
June 21, 2004


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600